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EXAMINER				
WOO, JILLAN W				
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/758,372
Filing Date: January 15, 2004
Appellant(s): SCHWARTZ ET AL.

Jeffrey T.G. Kelsey
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on March 15, 2010 appealing from the Office action mailed on October 13, 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-4 and 6-17.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonutti et al. (6,010,525). Bonutti et al. disclose, at least in figures 26-28 and col. 26, line 63 to col. 28, line 23; a device including a first anchor (540) having a locking mechanism (542) configured to grip and hold or lock a suture at any point along the suture; and a cannula (544) including a first lumen (578), the first anchor being shaped to seat below the first surface of soft tissue (54) or is capable of seating below the first surface of a meniscus, whereby proper seating of the device closes a defect without interfering with joint articulation; a second anchor (602) having a hole, and a suture (52), where the suture connects and first and second anchors by passing through the lumen of the cannula of the first anchor while traveling in a first direction, by passing through the hole of the second anchor, and by returning through the lumen of the cannula of the first anchor while traveling in a second and opposite direction, where tension on the suture pulls the second anchor toward the first anchor. Note: The introductory statement of intended use ("for repairing a defect in soft tissue" or a meniscus) has been carefully considered but deemed not to impose any structural limitations on the

claims patentably distinguishable over the device of Bonutti et al., which is capable of being used as claimed if one desires to do so.

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti et al. (5,383,905) in view of Wilk (5,391,173). Bonutti et al. disclose the invention substantially as claimed, where the suture also forms a loop with respect to the first anchor, where the lumen of the first anchor includes a first opening (at 594) defined in a first side of the first anchor and a second opening (582 or 584) defined in a second side of the first anchor, the first opening being larger than the second opening, and where the lumen of the first anchor is tapered (at 594). However, Bonutti et al. do not disclose that the first anchor has a frustoconical end shaped to bury into and seat below the first surface of the soft tissue. Wilk teaches, at least in figures 1, 2C, and 2D and in col. 3, line 66 to col. 4, line 2 and col. 4, lines 39-50; a suture anchor (8) including an external frustoconical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wilk, to modify the first anchor of Bonutti et al. so that it has a frustoconical shape or end-shape. Such a shape would provide a tapering surface for engagement of the anchor with a tool or by hand and allow sliding or pushing of the anchor along a suture and towards (or into) soft tissue.

(10) Response to Argument

With respect to Appellant's allegation on page 6, paragraph I.A., of the brief, that the device of Bonutti is not "shaped to seat below the first surface of soft tissue": The Appellant is incorrect. Appellant is reminded that the recitation that an element is "shaped" to perform a function only requires the ability to so perform. And given the

broadest reasonable interpretation of the phrase "below the first surface of soft tissue," Bonutti's first anchor (element 540) is indeed capable of being seated or positioned below soft tissue, if, for example, the orientation of soft tissue, as shown in figure 26, is turned upside down, such that first anchor 540 is deemed to be "below" the first surface of soft tissue. Bonutti's recitation of the anchor being "pressed against an upper side surface 98 of body tissue" is only referring to an instance where the orientation of the body tissue as shown in figure 26 results in the suture retainer being above the first surface of tissue. Certainly, a patient and his or her soft tissue may be oriented in various positions, and Bonutti's first anchor is configured to be oriented and fastened in place according to the position of a surface of the soft tissue—a position that may be deemed "below the first surface of tissue."

Moreover, Appellant discloses in the specification, on page 5, lines 4-20, that the anchors of the inventive device "may be located on opposite sides of a soft tissue defect" or may be buried "partially or totally into tissue." Bonutti's anchors (540 and 602), like the inventive device, are shown, in figure 26, to be on opposite sides of soft tissue—tissue that may be within a patient's body or is subcutaneous, where one of the sides of tissue may be deemed "below [a] first surface of tissue." Also like the inventive device, Bonutti applies tension to a suture to pull the anchors together and sandwich soft tissue therebetween. This tensioning would inherently result in at least the partial burial or embedding of an anchor within soft body tissue. This embedding of an anchor in tissue may also be deemed a seating of the anchor "below [a] first surface of tissue." In short, Bonutti's anchor is capable of seating below a surface of soft tissue as claimed.

With respect to the Appellant's allegation, on page 10, paragraph I.A., of the brief, that the final Office action failed to put forth any reasoning or evidence to show that Bonutti is capable of use with meniscus: The Appellant is incorrect, for Bonutti discloses in several places (e.g., figure 1 and col. 3, lines 60-67) a device applicable to "layers" of "body tissue" or "soft body tissue." Meniscus comprises layers of body tissue or soft body tissue. And since Bonutti is applicable to soft body tissue, even layered body tissue, one of ordinary skill in the art may infer that Bonutti is capable of use with meniscus.

With respect to the Appellant's allegation, on page 12, paragraph I.C., of the brief, that the final Office action failed to put forth any factual basis to show that Bonutti is capable of seating in tissue without interfering with joint articulation: The Appellant is incorrect. First, the Appellant has not specified, in the claims, which joint is being articulated when a device is seated in tissue, nor has the Appellant specified the size and configuration of the soft tissue or meniscus to be repaired. Bonutti's device is applicable to body tissue away from several body joints, so clearly, Bonutti's device is capable of being seated without affecting, say, a distant joint. However, assuming arguendo, that the Appellant is referring to the joint adjacent to meniscus: Again, Bonutti indeed discloses the capability of use with soft tissue, which may include meniscus by inference. Soft tissue or meniscus can come in various sizes and shapes. Moreover, anchors can obviously be chosen or sized, shaped, and positioned according to the sizes and shapes of tissue being treated and according to the location of a defect. Thus, depending on the meniscal or defect configuration and location, Bonutti's device

may be chosen and seated in tissue without affecting joint articulation. That is, Bonutti's device is capable of seating in tissue without interfering with joint articulation.

With respect to Appellant's allegation, on page 14, paragraph II.A., of the brief, that the final Office action proposes "to modify the opposite, non-tissue contacting end of [Bonutti's] suture retainer 540 [with Wilk] to have the frustoconical end": The Appellant is incorrect. First, as set forth above, Bonutti's device is capable of being seated below a surface of soft tissue. Moreover, Bonutti discloses the "flat circular bottom side" of suture retainer 540 is engaged with soft tissue. However, as pointed out in the rejection, Bonutti does not disclose that the suture retainer has a "frustoconical end shaped to bury into and seat below the first surface of the soft tissue." Nevertheless, Wilk provides a teaching of a suture anchor (8) with a frustoconical end, where the broad, flat circular bottom side of the anchor is engaged with soft tissue (just like Bonutti's device). Thus, as set forth in the rejection, Bonutti is modified to a frustoconical shape as taught by Wilk, where Bonutti and Wilk teach the large, bottom sides of their anchors, rather than narrow sides, being engaged with tissue, and where the anchors are configured to be "below" a surface of tissue (as defined above) or partially buried in soft tissue.

With respect to the Appellant's allegation, on page 16, paragraph II.B., of the brief, that the final Office action failed to put forth analysis or evidence to show that Bonutti in view of Wilk is capable of use with meniscus: The Appellant is incorrect, for as set forth above, Bonutti discloses a device applicable to layers of soft body tissue. Meniscus comprises layers of soft body tissue. And since Bonutti is applicable to

layered body tissue, one of ordinary skill in the art may infer that Bonutti in view of Wilk is also capable of use with meniscus. And depending on the sizes and shapes of a meniscus and of the anchors, one of ordinary in the art would apply the device of Bonutti in view of Wilk to a meniscus without undue protrusions into tissue.

Finally, with respect to the Appellant's allegation, on page 18, paragraph II.C., of the brief, that the final Office action failed to put forth any analysis or evidence to show that Bonutti in view of Wilk is capable of seating in tissue without interfering with joint articulation: The Appellant is incorrect. First, the Appellant has not specified, in the claims, which joint is being articulated when a device is seated in tissue, nor has the Appellant specified the size and configuration of the soft tissue or meniscus to be repaired. The device of Bonutti in view of Wilk is applicable to body tissue away from several body joints, so clearly, the device of Bonutti in view of Wilk, is capable of being seated without affecting, say, a distant joint. However, assuming *arguendo*, that the Appellant is referring to the joint adjacent to meniscus: Again, Bonutti in view of Wilk indeed discloses the capability of use with soft tissue, which may include meniscus by inference. Soft tissue or meniscus can come in various sizes and shapes. Moreover, anchors can obviously be chosen or sized, shaped, and positioned according to the sizes and shapes of tissue being treated and according to the location of a defect. Thus, depending on the meniscal or defect configuration and location, the device of Bonutti in view of Wilk may be chosen and seated in tissue without affecting joint articulation. That is, the device of Bonutti in view of Wilk is capable of seating in tissue without interfering with joint articulation.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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